Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (original): A device for the propagation of tissue comprising a bioartificial composite comprised of a substrate having at least one surface capable of the reception and growth promoting retention of a cellular preparation, and a first layer of adherent cells disposed on said surface, said first layer prepared from said cellular preparation, the cells comprising said first layer having cytoskeletal elements aligned uniformly, wherein said bioartificial composite acts as a template to accept a second layer of cells upon said first layer, said second layer comprising an organized layer oriented in the direction of said first layer, wherein said substrate has at least one surface defined by a critical surface curvature and/or topography.

Claim 2 (original): The device of Claim 1 wherein said substrate has at least one cell accepting surface defined by an oriented surface roughness of at least 200 nm root mean squared.

Claim 3 (original): The device of Claim 1 wherein said substrate has at least one cell accepting surface defined by a surface curvature of equal or greater than .016 microns^{-1}.

Claim 4 (original): The device of Claim 1 wherein said substrate defines a repeating surface structure.

Claim 5 (original): The device of Claim 1 wherein said bioartificial composite possesses an over all non-planar shape.

Claim 6 (original): The device of Claim 1 wherein said substrate is coated with a biocompatible, growth promoting preparation, which preparation minimizes non-specific protein binding and optimizes attachment of said cells.

Claim 7 (original): The device of Claim 6 wherein said preparation is selected from the group consisting of surfactants, cell adhesion molecules, polycations, cell growth factors, and mixtures thereof.

Claim 8 (original): A device for the preparation of implantable tissue comprising a bioartificial composite comprised of a substrate having at least one surface capable of the reception and growth promoting retention of a cellular preparation, and a first layer of adherent cells disposed on said surface, said first layer prepared from said cellular preparation, the cells comprising said first layer having cytoskeletal elements aligned uniformly, wherein said bioartificial composite acts as a template to accept a second layer of cells upon said first layer, said second layer comprising an organized layer oriented in the direction of said first layer, wherein said substrate has at least one surface defined by a critical surface curvature and/or topography.

Claim 9 (original): The device of Claim 8 wherein said substrate has at least one cell accepting surface defined by an oriented surface roughness of at least 200 nm root mean squared.

Claim 10 (original): The device of Claim 8 wherein said substrate has at least one cell accepting surface defined by a surface curvature of equal or greater than 0.016 microns^{-1}.

Claim 11 (original): The device of Claim 8 wherein said substrate defines a repeating surface structure.

Claim 12 (original): The device of Claim 8 wherein said bioartificial composite possesses an over all planar shape.

Claim 13 (original): The device of Claim 8 wherein said bioartificial composite possesses an over all non-planar shape.

Claim 14 (original): The device of Claim 8 wherein said substrate is coated with a biocompatible, growth promoting preparation, which preparation minimizes non-specific protein binding and optimizes attachment of said cells.

Claim 15 (original): The device of Claim 14 wherein said preparation is selected from the group consisting of surfactants, cell adhesion molecules, polycations, cell growth factors, and mixtures thereof.

Claim 16 (original): The device of Claim 8 wherein said bioartificial composite is defined by at least one filamentous substrate.

Claim 17 (original): The device of Claim 8 wherein said bioartificial composite is defined by at least one cylindrical substrate.

Claim 18 (original): The device of Claim 17 wherein said substrate has a diameter of less than 300 μm.

Claim 19 (original): The device of Claim 8 wherein said substrate of said bioartificial composite further defines an axially aligned surface topography, and is coated with cell attachment molecules; and a layer of cells attached to said molecules, which cells are adapted to undergo morphological rearrangement to align with the long axis of said substrate; and at least one second cell layer of different cells that attached to the free upper surface of said first layer, which is also adapted to undergo the same said morphological rearrangement.

Claim 20 (original): The device of Claim 19 wherein the morphological rearrangement of said first layer of cells which comprises the bioartificial composite is promoted and effected by the imposition of suitable force on said first layer and/or said substrate.

Claim 21 (original): A method for the preparation of the device of either of claims 1 or 8, which method comprises:

a. preparing a suitable biomaterial as a three dimensional structure selected from sheets, strips, strands of indefinite length and fibers;

b. treating at least one outer surface of the biomaterial prepared in Step a. to form thereon at least one said surface for the reception of said first layer of cells;

c. recovering said treated biomaterial defining the said at least one surface of Step b.;

wherein said biomaterial film of Step c. is adapted to serve as substrate for said device.

Claim 22 (currently amended): A method for the preparation of a bioartificial composite useful for repair of tissues or organs in a host, said method comprising:

a. preparing a substrate having ~~defining~~ a surface having the morphological characteristics of the desired tissue<u>s or organs said surface permitting the reception and growth promoting retention of a cellular preparation, wherein the cellular preparation comprises a quantity of cells capable of growth and aggregation to form a component of said tissues or organs</u>;

b. applying <u>the cellular preparation</u> to the surface of said substrate <u>to form a first layer of adherent cells disposed on said surface having cytoskeletal elements aligned uniformly, wherein said first layer acts as a template to accept a second layer of cells upon said first layer, said second layer comprising an organized layer oriented in the direction of said first layer</u> ~~a cellular preparation, said cellular preparation comprising a quantity of cells capable of growth and aggregation to form a component of said tissue~~; and

c. implanting the bioartificial composite of Step b. at the location of desired repair, whereby the growth of said tissue takes place in the host.

Claim 23 (original): The method of Claim 22 wherein said cellular preparation of Step b. is of a different cell type from that of said tissue.

Claim 24 (original): The method of Claim 22 wherein said cellular preparation of Step b. is genetically modified to deliver a therapeutic compound useful in the treatment of disease or the promotion of tissue repair.

Claim 25 (original): A method for the repair of damaged tissues or organs in a mammal comprising preparing a biological composite in accordance with the method of Claim 22.

Claim 26 (currently amended): A method for the preparation of tissue useful for repair of tissues or organs in a host, said method comprising:

a. preparing a substrate having ~~defining~~ a surface having the morphological characteristics of the desired tissue, said surface permitting the reception and growth promoting retention of a cellular preparation, wherein the cellular preparation comprises a quantity of cells capable of growth and aggregation to form said tissue;

b. applying the cellular preparation to the surface of Step a to form a first layer of adherent cells disposed on said surface having cytoskeletal elements aligned uniformly, wherein said first layer acts as a template to accept a second layer of cells upon said first layer, said second layer comprising an organized layer oriented in the direction of said first layer. ~~cellular preparation, said cellular preparation comprising a quantity of cells capable of growth and aggregation to form said tissue;~~

c. incubating the substrate of Step b. under conditions promoting the growth of said tissue thereon; and

d. recovering the tissue prepared in Step c.

Claim 27 (currently amended): A method for the preparation of tissue useful for testing, development and discovery, said method comprising:

a. preparing a substrate defining a surface having the following characteristics:

i. at least one cell accepting surface defined by an oriented surface roughness of at least 200 nm root mean squared;

ii. at least one cell accepting surface defined by a surface curvature of equal or greater than .016 microns^{-1}; and

iii. said substrate defines a repeating surface structure that enables cytoskeletal structures of cells applied thereto to become aligned uniformly;

b. applying to the surface of Step a. a cellular preparation, said cellular preparation comprising a quantity of cells capable of growth and aggregation to form a first layer of cells having uniformly-aligned cytoskeletal elements, the first layer being suitable to act as a template to accept a second layer of cells thereon and orient the second layer of cells in the direction of the first layer;

c. incubating the bioartificial product of Step b. with a different type of cell to effect growth of said tissue thereon; and

d. recovering the tissue prepared in Step c.;

wherein said tissue may be used as [[as]] a benchtop testing system or tissue surrogate.

Claim 28 (currently amended): A method for the preparation of tissue useful for repair of tissues or organs in a host, said method comprising:

    a. preparing a substrate defining a surface having the following characteristics:

        i. at least one cell accepting surface defined by an oriented surface roughness of at least 200 nm root mean squared;

        ii. at least one cell accepting surface defined by a surface curvature of equal or greater than .016 microns^{-1}; and

        iii. said substrate defines a repeating surface structure that enables cytoskeletal structures of cells applied thereto to become aligned uniformly;

    b. applying to the surface of Step a. a cellular preparation, said cellular preparation comprising a quantity of cells capable of growth and aggregation to form a first layer of cells having uniformly-aligned cytoskeletal elements, the first layer being suitable to act as a template to accept a second layer of cells thereon and orient the second layer of cells in the direction of the first layer;

    c. incubating the bioartificial product of Step b. with a different type of cell to affect growth of said tissue thereon; and d. recovering the tissue prepared in Step c;

    wherein said tissue may be used for therapeutic purposes.

Claim 29 (original): The method of Claim 28 wherein said cellular preparation of Step b. is genetically modified to deliver a therapeutic compound useful in the treatment of disease or the promotion of tissue repair.

Claim 30 (original): A method for the preparation of tissue useful for repair of tissues or organs in a host, said method comprising:

    a. preparing said tissue as in Claim 29; and

    b. implanting said tissue at the desired site for tissue or organ repair.

Claim 31 (original): The device of Claim 1 wherein said cellular preparation comprises cells taken from said host.

Claim 32 (original): The device of Claim 8 wherein said cellular preparation comprises cells from the tissues adjacent to the site of the implant of the device, that grow along said platform surface.

Claim 33 (original): The device of either of Claims 1 or 8 wherein said substrate is bioresorbable.

Claim 34 (original): The device of either of Claims 1 or 8 wherein said substrate is flexible.

Claim 35 (original): The device of either of Claims 1 or 8 wherein said cells comprise cells of the nervous system.

Claim 36 (original): The device of Claim 35 wherein said cells are derived from the CNS.

Claim 37 (original): The device of Claim 35 wherein said cells are selected from neurons, glial cells, astrocytes, microglial cells, dorsal root ganglion (DRG) cells.